JAN - 3 2001

K 003756

510(k) Summary
Bionc Implants Inc.'s
BioSorbFX and BioSorbPDX Tacks

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, PA 19422

Contacts: Gerard S. Carlozzi
President and Chief Executive Officer
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Quality Manager
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5629

Date prepared: November 20th, 2000

Name of the Device: BioSorbFX and BioSorbPDX Tack, Bioabsorbable Fixation Fasteners

Common or Usual Name:
Bioabsorbable fixation fastener, used with plates

Classification Name: Bioabsorbable fixation fastener, used with plates (Product Code 76 JEY)

Predicate Devices:
1. Bionx Implants, Inc. BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System ("BioSorbFX™ 1.5/2.0 System") (K982139)
2. Bionx Implants, Ltd. BioSorbPDX System (K000836)

Intended Use

BioSorbFX and BioSorbPDX Tacks are intended for use with plates in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton.

BioSorbFX and BioSorbPDX Tacks is not intended for use in and is contraindicated for: 1) the mandible; 2) full load bearing procedures; 3) areas with active infection; or 4) patient conditions, including blood supply limitations, insufficient quantity or quality of bone or latent infections.

Device Description and Principles of Operation

BioSorbFX Tack and BioSorbPDX Tack, Bioabsorbable Fixation Fasteners, are tack like devices, provided with two diameters, 1,5 and 2,0 mm and with two lengths, 4 and 6 mm. Design of the devices is identical, only difference is raw material. BioSorbFX Tack is intended for use with BioSorbFX 1.5/2.0 System Plates made of poly-L/DL-lactide copolymer and BioSorbPDX Tack is intended for use with BioSorbPDX System plates made of polylactideglycolide raw material. The purpose is amendment of an alternative fixation fastener to the shortest, 4-6 mm screws.

An instrument set consists of crossbow type tack inserter and bone drill. Crossbow type tack inserter utilizes the very same technology and principles than Bionx implants Inc. Crossbow® instrument introduced with Meniscus Arrow™ (K993453). Basic elements are the drilling of hole for the tack, which is completely the same step than with the conventional screws. Then the tack is pushed into hole with inserter. There is no need for tapping the hole and screwing like with the conventional screws.

Technological Characteristics and Substantial Equivalence

As noted above, BioSorbFX Tack and BioSorbPDX Tack are provided with two alternative raw materials, made of polylactide-glycolide copolymer and poly-L/DL-lactide copolymer. These raw materials are the very same than used in the previously cleared BioSorbPDX System (K000836) and BioSorbFX™ 1.5/2.0 System (K982139).

Bionx Implants Inc. BioSorbFX and BioSorbPDX Tacks and fixation fasteners included in BioSorbPDX System (K000836) and BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System (K982139) have the same intended use and principles of operation and very similar design characteristics. The minor technical differences between BioSorbFX and BioSorbPDX Tacks and the predicate devices do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2001

Bionx Implants, Incorporated
Mr. David W. Anderson
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Blue Bell, Pennsylvania 19422

Re: K003756
Trade Name: BioSorbFX and BioSorbPDX Tracks
Regulatory Class: II
Product Code: JEY
Dated: November 20, 2000
Received: December 6, 2000

Dear Mr. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K003756

Device Name: BioSorbFX and BioSorbPDX Tacks

Indications for Use:

BioSorbFX and BioSorbPDX Tacks are intended for use as plate fixation fasteners in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton.

BioSorbFX and BioSorbPDX Tacks are not intended for use in and is contraindicated for: 1) the mandible; 2) full load bearing procedures; 3) areas with active infection; or 4) patient conditions, including blood supply limitations, insufficient quantity or quality of bone or latent infections.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K003756

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003756